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10/538,913	09/29/2005	Andrea Venturelli	5659	5133
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EXAMINER MCEVOY, THOMAS M				
ART UNIT		PAPER NUMBER		
3731				
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11/17/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,913

Applicant(s)

VENTURELLI, ANDREA

Examiner

THOMAS MCEVOY

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 and 51-56 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-49 and 51-56 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Currently claims 1-49 and 51-56 are pending and considered below. Claims 50 and 57 have been cancelled.

Claim Rejections - 35 USC § 103

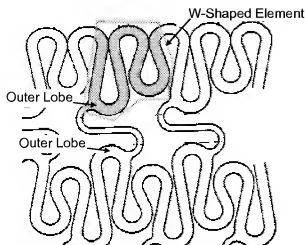
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

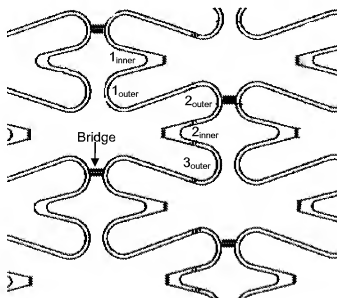
2. Claims 1-17, 19-21, 23-31, 34, 40, 41, 43-46, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (US 5,935,162) in view of Fischell et al. (US 6,540,775).

Dang discloses an expandable endolumenal prosthesis comprising, in the non-expanded configuration, a tubular body (Fig. 1), the tubular body having a porous wall defined by a plurality of interlaced circumferential lines forming a pathway motif or pattern (Fig. 2, item 30), in which at least one line is closed onto itself (Fig. 2; col. 4, lines 41-43), each of the lines extends along an axis (implicit for cylindrical sections as in col. 4, lines 41-43), each of the lines comprises at least one plurality of modules (Fig. 2; col. 4, lines 57-59), each module comprises three lobes, that is, two outer lobes and one inner lobe (inner and outer lobes can be defined arbitrarily in the prior art. Consider the lower left of Fig. 2; going from down to up, three bends define three lobes: The bend to the left adjacent to the bridge defines an outer lobe, the following bend to the right defines an inner lobe and the following bend defines an outer lobe) disposed between

the two outer lobes in the pathway of the pattern, each lobe comprising one or more curved sections having concavities facing in the same direction, defining an apex of the lobe (Fig. 2), the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (col. 5, lines 29-31), both of the outer lobes of the three lobes being extended by straight outer arms (Fig. 2), the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (Fig. 2), for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module (Fig. 2), for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (Fig. 2), at least one connecting element or bridge is provided between two adjacent lines (Fig. 3, item 50), and in which said bridge connects two faced outer lobes of two adjacent lines, said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body (Fig. 2). Dang does not disclose the bridges directly connect opposed outer lobes of adjacent lines wherein each bridge is provided between two adjacent lines, for every five complete lobes of a line, three outer lobes and two inner lobes. Fischell teaches using bridges to attach one outer lobe of opposing w-shaped modules for increased flexibility while allowing for the stent to have a reduced diameter upon crimping onto a balloon. See below:



Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell's bridges. Such a modification allows for improved flexibility and minimum crimpable diameter. Furthermore, since Dang discloses that the bridge (tie members) should connect modules ("w-shaped" elements) that open up towards eachother (Abstract; Figure 2), it would have been obvious to one of ordinary skill in the art to attach outer lobes (in view of Fischell) only to modules that open up towards eachother (in view of Dang). This would result in the structure shown below which meets the limitations of Applicant's claim 1.



Regarding claim 2, Dang discloses the inner lobe of at least one module being extended by at least one straight inner arm (Fig. 2). Regarding claim 3, Dang discloses both of the ends of the inner lobe being extended by straight arms (Fig. 2). Regarding claim 4, Dang discloses at least one of the outer arms extends along an axis which is inclined to the longitudinal axis of the tubular body and is also inclined to the axis of the line to which the module belongs (Fig. 2). Regarding claim 5, Dang discloses both of the outer arms of the module extend along respective axes which are inclined to the longitudinal axis of the tubular body and are also inclined to the axis of the line to which the module belongs (Fig. 2). Regarding claim 6, Dang discloses the outer arms of the module extend away from the lobes along converging axes (Fig. 2). Regarding claim 7, Dang discloses the arms have inclinations substantially close to the direction of the longitudinal axis of the prosthesis when the prosthesis is in the non-expanded configuration (Fig. 2). Regarding claim 8, Dang discloses the inclination of the arms is selected in a manner such that, when the prosthesis is in the expanded configuration, the arms are arranged substantially close to the direction transverse the longitudinal axis of the prosthesis (Fig. 2). Regarding claim 9, Dang discloses at least one outer arm of a module is shared with the adjacent module (Fig. 2). Regarding claim 10, Dang discloses all of the outer arms of each module are shared with adjacent modules (Fig. 2). Regarding claim 11, Dang discloses the outer arms are of equal extent (Fig. 2). Regarding claim 12, Dang discloses the inner lobe being extended by two straight inner arms (Fig. 2). Regarding claim 13, Dang discloses the inner arms are of equal extent (Fig. 2). Regarding claim 14, Dang discloses the inner lobe is joined to the outer lobes

by means of at least one inner arm (Fig. 2). Regarding claim 15, Dang discloses the inner lobe and the inner arm or arms have an overall extent less than the overall extent of the outer lobes and the respective outer arms (Fig. 2). Regarding claim 20, Dang discloses at least one module has two inner arms of equal extent (Fig. 2). Regarding claim 23, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for determining the aperture of the cell which faces it (Fig. 2). Regarding claim 24, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially parallel to the longitudinal axis of the prosthesis when it is in the non-expanded or clenched configuration (Fig. 2). Regarding claim 25, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially transverse the longitudinal axis of the prosthesis when it is in the expanded configuration (Fig. 2). Regarding claim 26, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation (Fig. 2). Regarding claim 27, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation and at least one interposed straight section (Fig. 2). Regarding claim 28, Dang discloses the inner lobe is joined directly to one of the outer lobes (Fig. 2). Regarding claim 29, Dang discloses all of the modules of a line have identical characteristics (Fig. 2). Regarding claim 31, Dang discloses in at least one line, the same module is repeated along the pathway of the line in a mirror-image

arrangement with respect to an axis parallel to the axis of the line (Fig. 2). Regarding claim 40, Dang discloses at least one module is substantially M-shaped and is arranged so as to have outer arms directed substantially either towards the distal end or towards the proximal end (Fig. 2). Regarding claim 41, Dang discloses the axis of the line is substantially perpendicular to the longitudinal axis of the tubular body (Fig. 2). Regarding claim 43, Dang discloses the line axis is straight or circumferential (Fig. 2). Regarding claim 44, Dang discloses for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (Fig. 2). Regarding claim 45, Dang discloses at least one connecting element or bridge is provided between two adjacent lines (Fig. 3 Item 50). Regarding claim 46, Dang discloses the bridge defines the interlacing of the lines (Fig. 2). Regarding claim 51, Dang discloses along the line, a bridge is provided between two adjacent lines, for every first or second outer lobe having the same orientation (Fig. 3 Item 50). Regarding claim 52, Dang discloses a bridge is provided for every module of the line (Fig. 2). Regarding claim 53, Dang discloses between two adjacent lines, a continuous closed pathway is provided, disposed between two bridges defining a cell (Fig. 2).

Regarding claims 16, 17, 19, 21, 30, and 34, Dang does not disclose the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line; the outer or inner arms have an extent which varies in the modules of the same line; the outer arms of the same module have different extents; at least one module has two inner arms of different extents; in at

least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality; at least one module has outer lobes that are disposed at different distances from the axis of the line. Fischell et al. teach that the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line (Fig 1 L3); the outer or inner arms have an extent which varies in the modules of the same line (Fig 1 19L and 19M); the outer arms of the same module have different extents (Fig 1 19L and 19M); at least one module has two inner arms of different extents (Fig 1 19S and 19L); in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality (Fig. 1, as one example: one module begins with Item 24MC and ends at Item 24MU, the next module begins immediately following Item 24MU and encompasses three lobes); at least one module has outer lobes that are disposed at different distances from the axis of the line (Fig 1 L3). Regarding claim 16, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callot et al.'s non-uniform extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 17, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s varied extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 19, it would have been obvious to

a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s outer arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 21, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s inner arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 30, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s two pluralities of modules. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel. Regarding claim 34, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s outer lobes. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

3. Claims 18, 22, 32, 33, 35-39, 47-49, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang '162 in view of Fischell '775 as applied to claim 1, and further in view of Callol et al. (US 2002/0183763).

Dang and Fischell disclose the invention substantially as claimed as stated above. They do not disclose the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis; at least one module having a single inner arm; in at least one line, the pathway is interrupted so as to form an opening in the pattern suitable for the passage of an SDS

guide wire; the pathway is interrupted to an extent equal to one module; the pathway is interrupted to an extent equal to five lobes; the pathway is interrupted between two connecting bridges between the line and adjoining lines; the pathway is interrupted in two adjacent lines; the bridge comprises a bridge lobe; the bridge comprises two bridge lobes; the bridge comprises three bridge lobes. Callol et al. teach that the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis (Fig. 7A Items 26, 28, and 29); at least one module has a single inner arm (Fig 8 Item 28); the prosthesis comprises lines comprising several pluralities of modules (Fig 7A Item 28 and top line of Item 29); the prosthesis comprises three pluralities of modules (Fig. 7B Item 45, Item 34, and the module directly above Item 34); in at least one line, the pathway is interrupted so as to form an opening in the pattern (Fig. 8 Item 40); the pathway is interrupted to an extent equal to one module (Fig. 8 Item 40); the pathway is interrupted to an extent equal to five lobes (Fig. 8 Item 40); the pathway is interrupted between two connecting bridges between the line and adjoining lines (Fig. 8 Item 40); the pathway is interrupted in two adjacent lines (Fig 8 Item 40); the bridge comprises a bridge lobe (Fig. 21 Item 33); the bridge comprises two bridge lobes (Fig. 21 Item 33); the bridge comprises three bridge lobes (Fig. 21 Item 33); a variation of the cell perimeter is provided along the longitudinal axis of the prosthesis (Fig 7A Item 28). Regarding claim 18, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s varied extent. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the

side branch vessel. Regarding claim 22, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s single inner arm. Such a modification would allow for the passage of a balloon. Regarding claim 32, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel. Regarding claim 33, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s three pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel. Regarding claims 35-39, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s interruption. Such a modification would allow for the passage of a balloon. Regarding claims 47-49, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s bridge lobes. Such a modification would enhance the flexibility of the stent. Regarding claim 54, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s variation of cell perimeter. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

4. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang '162 in view of Fischell '775 as applied to claim 1 and 41, and further in view of Moore (US 2002/0065547).

Dang and Fischell disclose the invention substantially as claimed as stated above. They do not disclose the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees. Moore teaches the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees (Fig 1 a line forming a pathway motif can be defined by the two points 40 and 15. Its inclination is about 30 degrees). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Moore's angle. Such a modification would give the stent superior flexibility characteristics.

5. Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang '162 in view of Fischell '775 as applied to claim 1, and further in view of Ragheb et al. (US 6,299,604).

Dang discloses the invention substantially as claimed as stated above. Dang does not disclose the prosthesis comprises an external or internal coating; the coating comprises a drug. Ragheb et al. teaches the prosthesis comprising an external coating (col 3, lines 6-18) and the coating comprising a drug (col 3, lines 6-18). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the

invention was made to modify Dang's stent to include Ragheb et al.'s drug coating. Such a modification would allow a drug to be applied at the site of injury.

Response to Arguments

6. Applicant's arguments filed July 17th 2008 have been fully considered but they are not persuasive. Applicant argues that Fischell discloses that every outer lobe is connected by a bridge and therefore one would connect every outer lobe of Dang to apply the teachings of Fischell. Examiner respectfully disagrees and believes, as illustrated above, that Fischell teaches connecting one arm from each w-shaped element. Examiner believes that the closest matching structure in Fischell to the "w-shaped" elements disclosed by Dang are those illustrated above where the inner lobe is oriented in an opposite direction to the outer lobes (as in the instant Application). The w-shaped elements which Applicant has interpreted from Fischell have the inner lobes oriented in the same direction as the outer lobes. In Examiners opinion, this is not the structure in Fischell from which one would most likely apply the bridge teachings to the w-shaped elements in Dang.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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TM

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731